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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,025	06/30/2003	Hirokazu Ohbayashi	239546US0CONT	8296

22850 7590 10/04/2005

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,025	Applicant(s) OHBAYASHI ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/30/03, 3/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because legal phraseology such as “at least one of said two or more” is used. (See line 6) Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1 and 2 are rejected under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1 (3), “to other substance(s)” is vague and indefinite. It is unclear what “other substance(s)” applicants refer to.

Similarly, claim 2 (3) shares the same problem with claim 1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-26 are rejected under 35 U.S.C 102 (a) as anticipated by Ohbayashi et al. (USP 6252053).

Ohbayashi et al. teach an enzyme-carrier-antibody complex for immunoassay (See claim 1; Col. 3, line 10-18 and claim 10) Ohbayashi et al. teach conjugation carrier-enzyme or carrier-antibody by introducing either thio group or maleimide group to the carriers or enzymes. The process involves conjugating the antibody and enzyme via a carrier where the free amino groups on the carrier to which enzyme bound, for subsequent binding of antibody to the same carrier (Col. 2, line 47; Col. 5, line 30-31, line 50-51).

With respect to claim 2, the complex of Ohbayashi et al. are directly conjugated to the carrier (Col. 2, line 47; Col. 5, line 30-31, line 50-51).

With respect to claims 3-6, Ohbayashi et al. further teach selecting carriers of molecular weight ranging from 5,000-500,000 or 10,000-300,000 (See Col. 3, line 29-54).

With respect to claims 7-8, Ohbayashi et al. teach using free amino groups on the carrier for conjugation (Col. 2, line 47; Col. 5, line 30-31, line 50-51).

With respect to claims 9-12, Ohbayashi et al. teach using peptide polymers, i.e. polysine, containing amino groups or polysaccharide having aldehyde or amino groups as carriers (Col. 3, line 29-54).

With respect to claims 13-14, Ohbayashi et al. also teach using radish peroxidase, alkaline phosphatase, beta-galactosidase and glucose oxidase as enzymes source for immunoassay (See claim 2).

With respect to claims 15-20, Ohbayashi et al. teach use antibody and fragment(s), i.e. F(ab')₂, Fab' or Fabc' and streptavidin (See Col. 4, line 58-67 and Col. 7, line 50-54).

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With respect to claims 23-26, Ohbayashi et al anticipate the immunoassay kit because the reference discloses the complex as recited in claims 1 and 2. Further, Ohbayashi et al disclose immunohistochemistry and enzyme immunoassay. (See Col. 8, "Merit of the Invention") Accordingly, all the elements recited in the instant claim invention can be found out from the teachings of Ohbayashi et al.

3. Claims 1, 13, 15, 17 rejected under 35 U.S.C. 102(b) as being anticipated by Bohannon et al. (US 5763158).

Bohannon et al. teach a method for simultaneously testing a sample for the presence of multiple target molecules. Bohannon et al. teach use of a complex comprises a carrier, an enzyme conjugated to the carrier, and a protein with specific binding potency to other substance(s), where the protein is conjugated to the enzyme (See Figure 1).

With respect to claim 13, Bohannon et al. teach that the enzyme can be of horse peroxidase, alkaline phosphatase, or glucose oxidase (Col. 4, line 1-5).

With respect to claims 15, 17, 19, Bohannon et al. teach that the protein with specific binding potency is a polyclonal antibody or monoclonal antibody (See Figure 1-2; claim 4).

With respect to claims 23, 25, Bohannon et al. teach that the method can be applied to enzyme immunoassay or immunohistostaining (See Abstract; Summary Invention).

Conclusion

6. No claim is allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

Art Unit 1641



LONG V. LE

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600

09/13/05
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